



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/507,452

04/12/2005

Shishan Ji

1547/3

1381

25297 7590 03/23/2010
JENKINS, WILSON, TAYLOR & HUNT, P. A.
Suite 1200 UNIVERSITY TOWER
3100 TOWER BLVD.,
DURHAM, NC 27707

EXAMINER

WHEELER, THURMAN MICHAEL

ART UNIT

PAPER NUMBER

1619

MAIL DATE

DELIVERY MODE

03/23/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/507,452	Applicant(s) JI ET AL.	
	Examiner Thurman Wheeler	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-59 are pending in instant application

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 1-5, 7-9, 13, 15-30, 36-49, 52, 53, 57, and 58 drawn to a Y-shaped branched hydrophilic polymer derivative.

Group II. Claims 6, 50, 51, 54-56, and 59 drawn to a Y-shaped branched polyethylene glycol polymer derivative.

Group III. Claims 10-12, and 31-35 drawn to methods to prepare PEG derivatives.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because,

Art Unit: 1619

under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-II lack unity because they do not share the same technical feature. The representative chemical structure for compounds drawn to Group II contains a carbonyl group in the position that would be X₂ in group I, but group I does not embrace this substituent. Therefore, unity of invention between Groups I-II is broken.

Under PCT rule 13.1 and 13.2 since, as provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Furthermore, according to 37 CFR 1.475(c):

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

In addition, according to 37 CFR 1.475 (e):

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Since the Group I is directed towards Y-shaped branched hydrophilic polymer derivatives and Group II is directed towards Y-shaped branched polyethylene glycol polymer derivatives, whereas Group III is directed to methods to prepare PEG derivatives, it follows that Groups I-II are drawn to separate categories of invention as compared to Group III. Furthermore, the method used for pegylation of the Markush groups of Claims 1, 4, 5, and 6 could be used to attach polyethylene glycol units

Art Unit: 1619

to varied phospholipids, e.g. dipalmitoylphosphatidyl-ethanolamine (Harris et al USP 5672662, of record in the application, example 15, col.14).

Therefore, the unity of invention is broken.

Election of Species

2. Instant application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species specifying each of the variables shown in the formula(s) in claims 1, 4, 5, and 6 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 6 are generic.

If Group I is elected, the following species election is required: specifying each of the variables;

Claim 1: P_a , P_B , j , R_i , X_1 , X_2 , and F

or, Claim 4: P_a , P_B , (n and j), R_i , X_1 , X_2 , and F

Or, Claim 5: P_a , P_B , (n , m , and j), R_i , X_1 , X_2 , and F

If Group II is elected, the following species election is required: specifying each of the variables;

Claim 6: P_a , P_B , n and j , R_1 , X_1 , X_2 , F

Further, Applicants' are required to elect a single species from a conjugate formed by reacting the derivatives of claims 1, 4, 5, or 6 with a drug molecule through the terminal F as drawn to claim(s) 15, 37, 44, and 51, where the drug (species) is selected from the group consisting of:

- (a) amino acids, (b) proteins, (c) enzymes,
- (d) nucleosides, (e) saccharides, (f) organic acids,
- (g) glycosides, (h) flavonoids, (i) anthraquinones,
- (j) terpenoids, (k) phenylpropanoid phenols,
- (l) steroids, (m) glycoside of the steroids, and
- (n) alkaloids of the steroids.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The members of a Markush group are considered to have unity of invention when the following criteria are fulfilled:

(A) all alternatives have a common property or activity;

AND

(B) (1) a common structure is present, that is, a significant structural element is shared by all of the alternatives; OR

(B) (2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

However, the listed do not share a common structural feature (eg, organic acids, nucleosides and proteins have different structures) or belong to an art recognized recognized class of compounds.

Applicants are advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

Art Unit: 1619

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 5 809.02(a).

3. The examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and the product and use claims are subsequently found allowable, withdrawn method and use claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected method or use invention must require all the limitations of an allowable product claim for that method or use invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method and use claims will be withdrawn, and the rejoined method and use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims, method and use claims may be maintained. Withdrawn method or use claims that are not

Art Unit: 1619

commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the method and use claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thurman Wheeler whose telephone number is (571)270-1307. The examiner can normally be reached on Monday-Thursday, 7:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1619

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635